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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,238	06/04/2001	Jens Chr. Jensenius	09011-002003	6910

1444 7590 05/27/2003

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

874238

Applicant(s)

JENSENIUS et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 2/11/03
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 18-23, 26, 37, 40-43 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 18-23, 26, 37, 40-43 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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The claims pending are 18-23 26, 37 and 40-43.

Since Groups I and II can be searched without extensive search/examination burden, all claims are under examination.

Claim 37 is objected to under 37 CFR 1.75 (I) for failing to indent each step of the assay - e.g. "obtaining", "measuring".

Claims 18-23, 26, 37 and 40-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is confusing as to what the administered antigen is named. It is believed that, in line 3, "MASP-2 polypeptide" should be placed within parentheses.

In claims 19 and 42 the term "selectively binds" has not been defined in the specification. Does this term encompass cross-reactive binding? Would this encompass binding to a glycosyl epitope common to both MASP-2 and another protein? To more specifically point out applicant's invention, it is suggested applicant instead recite "--specifically binds--", which term has been defined in the specification at page 11".

In claim 23, line 7 "said complexes" lack antecedent basis.

Claims 40 and 42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite new matter.

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Claim 40 recites new matter because the examiner finds no teaching of an antigenic peptide of a length of 16 amino acids, in the teachings pertaining to the production of antibodies (pages 11 and 31). Where a peptide of 16 amino acids is mentioned (page 10) the teachings pertain to a reference peptide and not to an antigenic peptide.

Applicant would more broadly claim, with respect to peptide length, by reciting after “includes” --a determinant containing fragment, of SEQ ID NO: 2.--. This recitation would be supported at page 9.

Claim 42 contains new matter by reciting “selectively binds to the serine protease domain”. The examiner cannot find where there is literal support for an antibody directed against this particular domain. Where there may be conceptional support (page 42) applicant teaches antibodies directed against the “active site”, which is more narrow than “the serine protease domain” and which have inhibitory activity. Since the antibody of claim 42 is not required to have inhibitory activity, applicant is claiming more broadly than can be supported by the original disclosure.

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 26 lacks enablement for the measurement of “MASP-2 activity”.

Assuming that “MASP-2 activity” means enzymatic activity, as disclosed at page 36, lines 12+, the mere binding of antibody to MASP-2 cannot quantitate “MASP-2 activity”.

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Antibody binding to any enzyme merely gives a measure of the total amount of enzyme protein (active and inactive) present in a sample and does not give a measure of enzymatic activity, which must be measured by conducting an enzyme reaction and measuring disappearance of substrates, or the appearance of products.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 18-19, 22-23 and 40 are rejected under 35 U.S.C. 102(a) as being anticipated by Thiel et al. (Nature, 386, 606, 1997).

Thiel et al. show an antiserum to a peptide representing the 19 N-terminal amino acids of MASP-2. They also show an antiserum against a mixture of C terminal peptides (representing positions 505-523 and 538-556). See page 509, col. 2.

Though the Thiel et al. publication has an even date (4/3/1977) with that of provisional application 60/042,678, anticipation is stated because applicant's provisional Application does not support the instant claims. As far as can be ascertained the provisional application is a verbatim copy of the Thiel et al. Nature publication and discloses no broader. A

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mere disclosure of antisera against particular N and C-terminal peptides cannot support claims to any kind of antibody against any portion of MASP-2.

The above noted antisera thus anticipate instant claims 18-19 and 40. Claim 22 is included because any conventional diluent, which must inherently be present to conduct an antigen-antibody binding reaction, would also serve as a pharmaceutically acceptable carrier.

Claim 23 is included because the blotting studies conducted with the antisera of Thiel et al. may reasonably be considered as being conducted upon a "biological sample". Applicant has given no specification definition of this term to indicate that it should be more narrowly interpreted.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the

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organization where this application or proceeding is assigned is
(703) 308-4242.

Any inquiry of a general nature or relating to the status of
this application or proceeding should be directed to the
receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

May 12, 2003

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182-1644